

Wednesday, July 29, 2009

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>

Questions on SPL:

ER/DL regulatory questions? Send to edrls@fda.hhs.gov

SPL technical questions? Send to spl@fda.hhs.gov

Meeting Minutes:

Q&A session (Lonnie Smith from FDA will be joining us for this discussion)

- **Update from Weekly FDA SPLr4 Q&A sessions**
- **Open Q&A**

Q: How much of the current process [ESG -> eList -> DailyMed, NDC Code Directory, etc] is automated?

A: The connection between the ESG and the eList system is automated. The files going to DailyMed is not an automated process yet. The files going to NDC directory is not an automated process yet.

FDA is planning to launch its own website (currently the prototype is called Facts@FDA) with all labels in SPL. Look for additional search criteria, like imprints.

Q: How long should we wait to contact SPL mailbox if labels have not appeared on Daily Med

A: Going to DailyMed is not an automated process yet. Currently, expect a 24-48 hour delay.

Q: If the active ingredient has changed, does the product need a new NDC code

A: If the active ingredient name has changed, but not the actual ingredient, that would not require an NDC code change. If an inactive ingredient changes, that's considered a regulatory change, and should require a NDC code change.

Q: What happens if you have an R3 label on DailyMed that has packaging XML errors, and you have an R4 label that needs to 'write over' that R3 file.

A: Contact SPL@fda.hhs.gov with the setid and name of the R3 file, and the CoreID for the R4 file being sent.

Once the R4 label is in the eDRLS system, the manual 'write over' process is no longer available.

Q: When there are multiple prior approval submissions are at the FDA, how do we know what version to use?

A: This is one of the reasons that the FDA is no longer modifying the effective time and version information. These fields are now under the responsibility of the sponsor. That way, the sponsor can manage the versioning of the SPL.

Q: Does the effective time field need to be changed with each version change?

A: This field are now under the responsibility of the sponsor. The validation rules do not check for a change in effective time.

Remember that setids must remain the same across the lifecycle of the label document.

Q: Medication Guide as a subsection – why is this causing a validation error? Currently, we have some approval letters that specifically reference a subsection for Medication Guides. So if we adjust the SPL to prevent the validation error, we are now out of compliance with the Approval Letter [and in danger of misbranding]

A: The Review Divisions in CDER received notice recently that Medication Guides should not be subsections of the label/SPL.

Q: Carton / container labels included in the draft SPL – is this an error? We are trying to reduce duplicate SPLs

A: Review Division has received training in this situation

Q: Distributor/labeler looks like it changed (because of the DUNS number assignments and resulting company name presentations). Some reviewers are asking about possible name changes.

A: Review Division has received training in this situation. They are beginning to learn that the SPL file is being shared between the Review Division and the DRLS groups. The reviewers

Q: Is there any way that we can get signed up for Session 12?

A: Session 12 is full. The training sessions have been restructured. We have Sessions 23 and 24 now available. In the future, there will be a training session on the conversion from R3 to R4.

Q: Generic company receives notice that the RLD label is updated. SPL has been filed with the FDA prior to the update. Does the version number and docid need to be changed.

A: Those fields are not being checked during the Application Review process. Only during the Drug Listing process. So the version does not have to be incremented until the file gets Drug Listed again.

Q: Pending CBE changes [referencing text in approval letter that says

“In addition, within 21 days of the date of this letter, amend any pending applications for these NDAs with content of labeling in structured product labeling (SPL) format to include the changes approved in these applications.”

A: Allows the project manager to compare all of the changes in one document. Some reviewers are using the SPL during their review process.

This request asks for changes to SPL to be submitted to all pending applications.

Q: Prior approval submission six months ago. Two CBEs have been submitted since then. We're asking the Review Division to include the not-yet-approved text from the other CBE in the final printed label. Is this acceptable?

A: The Review Division is asking for the Final SPL after approval. The version on DailyMed should be the one that is currently in use.

Q: What if I have a label that isn't being used in packaging for several months? Should I still file Drug Listing immediately after approval.

A: The SPL can be Drug Listed immediately with a marketing start date three months in advance. Alternatively, the SPL can be Drug Listed at the time of use.

Q: Is there a need to close the gap between DailyMed and Drugs@FDA? Impression is that DailyMed is not as visible as Drugs@FDA.

A: Drugs@FDA is tightly linked to the approval cycle. You need to know the supplement number in order to even navigate to the label.

Q: Impression is that DailyMed is not as visible as Drugs@FDA.

A: Visibility of DailyMed – last count, 4.6 million hits per month for Drugs@FDA. DailyMed already has 2 million hits per month (only three years since implementation).

Q: Is there any guidance on the official FDA PDF version available from the DailyMed site?

A: NLM amends the SPL records with additional links. The FDA provides SPL as a zip file to NLM.

Q: Where did the requirement for carton images come from?

A: Requirements for carton images come from law and drug listing regulation.

Q: How many labels are you expecting? For instance, if I have five strengths and three pack sizes, do I need to send 15 labels.

A: Representative sample is what's required for the FDA. It is the sponsor's responsibility to determine what constitutes representative sample.

Q: Where does it state that you must send the SPL to the Office of the Commissioner?

A: In the Final Guidance, it tells you that you send the SPL through the Electronic Submissions Gateway (ESG). It also references the Step-by-Step instructions for further details. Section 5 of these instructions details the OC as the addressee.

Q: Would we be notified if the UNII had been assigned? Or do we need to regularly check the list of UNIs?

A: It depends on the complexity of the substance. It may take a while to assign the UNII. SPL group often responds to the person making the request.

Q: What happens if a UNII is missing – how can I Drug List?

A: For active ingredients, the SPL must have a UNII code for each active ingredient. For inactive ingredients, if the UNII code has not yet been assigned, leave the text of the inactive ingredient until the UNII is received.

Q: We are getting receipts and acknowledgements, but not seeing the files on DailyMed. We're not sure if we are receiving a second acknowledgement.

A: Check each acknowledgement to see if there might be a second acknowledgement (which would be an error message)

Q: Second acknowledgement.

A: If you upload the file against the Pragmatic validator, it will show you the error message and location of error.

Also, the second acknowledgement (with error information) is an [xml file](#).

Q: Limitations of the Pragmatics validator

A: The validator can't check against internal FDA databases. So DUNS number and version number checks aren't possible via the Pragmatics validator.

Training sessions

DIA – August 11 – 12 check at www.diahome.org for more information.

GphA – tbd, October

FDA is continuing to hold a variety webinar training sessions. See <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm> for more information.

Additionally, FDA is holding technical calls from 11:30 - 12:00 every Monday, except for Federal holidays, through December 28, 2009

Audio conference details: Telephone number: 1-866-775-9435//Participant pass code: 2219058

SPL STARTER PACKAGE:

Link to UNIIIs, information about vendors, useful files

Next meeting scheduled for Wednesday, Aug 12, 2009 from 1 – 2:30.

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